



REMARKS

The Pending Claims

Claims 18-28, 31-35, 39 and 40 are pending in this application, and are currently under final rejection.

The Office Action

In the office action mailed October 24, 2000, as in the previous office action, the Examiner noted that the specification included the trademarks "S SEPHAROSE FAST FLOW," "Q SEPHAROSE FAST FLOW," "STIRRED CELL" and "MARUMERISER," pointing out that the trademarks should be capitalized and accompanied by generic terminology wherever used. Applicants again acknowledge the Examiner's comments and will make all such corrections to the specification upon notification of allowable subject matter.

As in the previous office action, the Examiner rejected claim 18 under 35 U.S.C. § 112 as indefinite, based on the use of the term "processing" and also based on the use of "FTU/g" to report the concentration of the phytase solution.

The Examiner rejected claims 18, 19, 21, 22, 25-28 and 31-35 under 35 U.S.C. § 103 as obvious over Hamstra in view of Nevalainen and Jane, arguing that Hamstra teaches a method of making feed pellets by adding phytase to the pellets. While the Examiner acknowledged that Hamstra does not teach the composition of the pellets, beyond stating that they are composed of an edible material, the Examiner argued that Nevalainen teaches a highly active *A. niger* phytase and the use of phytases in animal feed, while Jane teaches a composition comprising a starch aldehyde and polyvinyl alcohol that may be pelleted for use as an animal feed. Jane does not teach the use of a phytase.

Additionally, the Examiner rejected claim 20 under § 103 as obvious over Hamstra, Nevalainen and Jane, further in view of Overton, arguing that Overton teaches the use of calcium in animal feed.

The Examiner also rejected claim 24 under § 103 as obvious over Hamstra, Nevalainen and Jane, further in view of Bedford, arguing that Bedford teaches a feed additive comprising xylanase, β -glucanase and phytase.

Finally, the Examiner entered several new rejections not previously entered as a basis for rejection of the pending claims. The Examiner rejected claims 23, 39 and 40 under 35 U.S.C. §

103(a), over Hamstra, in view of Nevalainen and "Grabitz." However, the office action includes no further reference to Grabitz and a copy of Grabitz was not included with the office action. Therefore, Applicants are unaware of the identity of this reference and have been unable to evaluate the reference to formulate a response. Applicants have responded on the basis of the information available and believe that the rejections have been overcome. To the extent the Examiner disagrees, however, Applicants request that the Examiner provide further information concerning the Grabitz reference and that Applicants be allowed to respond to the rejections based thereon.

The Claim Amendments

Claims 18 and 19 have been amended to more clearly define the scope of the invention. These amendments do not include new matter.

Response to Office Action

Section 112 Rejections

The Examiner has rejected claim 18 under 35 U.S.C. § 112, based on the use of the term "FTU/g." Applicants continue to believe that the use of "FTU/g" to report the phytase activity is appropriate and sufficiently clear to convey to one of ordinary skill in the art that the weight referred to in "FTU/g" is the weight of the aqueous phytase solution and not the specific activity of the phytase. Nonetheless, Applicants have amended claims 18 and 19 to specify that the term FTU/g refers to "FTU per gram of aqueous solution." The claims clearly indicate that the reference is to the concentration of the phytase in the aqueous solution, and no further confusion can be alleged. Accordingly, Applicants request that the rejection of claim 18 under § 112 be withdrawn.

Section 103 Rejections

Applicants respectfully traverse the Examiner's rejection of the pending claims under section 103, as none of the cited references, taken alone or in combination, teaches or suggests the claimed invention.

As discussed in the previous response, Hamstra relates to feed pellets, but does nothing more than mention phytase as an example of enzymes that may be included in the pellets. Hamstra teaches nothing concerning the activity of the phytase and, as the Examiner correctly notes, teaches nothing about the composition of the pellets, other than to state that they comprise edible material.

Applicants have previously pointed out that Nevalainen fails to disclose phytase having the activity recited in the present claims. As discussed previously, Nevalainen reports phytase activity

in “phytase units” (PU), defined as “the amount of enzyme which liberates, under standard conditions, 1 nmol of inorganic phosphate from sodium phytate in one minute” (p. 28, lines 7-9). In other words, Nevalainen reports phytase *specific activity*, whereas the pending claims relate to the concentration of phytase in an aqueous solution, in units of FTU per gram of aqueous solution. The specification of the present application defines FTU as the amount of enzyme which liberates 1 μ mol of phosphate in one minute (p. 4, lines 19-21). Both units are based substantially on the same conditions of temperature, pH and phytate concentrations (*see* Nevalainen, p. 28, lines 10-14 and the instant specification at p. 4, lines 19-21). Therefore, 1 FTU essentially equals 1000 PU.

Referring to Table 1 of Nevalainen, the Examiner argues that the “Mono S fraction” reported therein discloses phytase activity of “275,885 Units/g”. It is, however, difficult, if not impossible to determine the concentration of the phytase per weight or volume of liquid because the volume of the fractions reported in Table 1 is omitted. Nevalainen does not describe the volume of the Mono S fraction referred to by the Examiner. This fraction was eluted using a linear salt gradient spread over 20 ml and, therefore, it is reasonable to assume that at least 20 ml of buffer was used to elute the Mono S fraction and that the volume of this fraction was at least 20 ml. Even if the volume were only 20 ml, and the volume of buffer used may have been considerably more than this, one must divide the total activity (PU) figure of 827,566 by 20, giving an activity of 41,378 PU/ml, which converts to 41.378 FTU/ml. Although, as discussed in the previous response, the conversion from FTU/ml to FTU/g is approximate at best, it still can be seen that the *concentration* of phytase in the Mono S fraction is several orders of magnitude below that claimed by amended claims 18 and 19.

Moreover, the specific activity reported by Nevalainen cannot even be used to estimate the concentration of phytase, since it is not a measure of the activity per unit of phytase, but is only a measure of the phytase activity per unit of protein, much of which may not be phytase. Without knowing the volume of a particular fraction, such as the Mono S fraction, it is impossible to determine the concentration of the phytase in such fraction. Accordingly, Nevalainen fails to disclose a phytase preparation having a concentration as claimed.

The Examiner argues that Jane discloses a composition comprising a protein and a starch aldehyde and that other additives may be added to the already cross-linked product, including enzymes, arguing that Jane *et al.* do not suggest that further cross-linking will take place. With

respect, there is nothing in Jane to suggest that additional cross-linking *will not* take place and, indeed, Jane includes no teaching of any composition that includes an active enzyme.

Although Applicants have not seen the Grabitz reference cited by the Examiner in reference to claims 23, 39 and 40, in view of the deficiencies of Nevalainen, the disclosure of the Grabitz reference cited by the Examiner does not appear to render the claimed invention obvious. The Examiner admits that "Grabitz does not teach a phytase-containing pellet" and, therefore, although Applicants request the opportunity to review and comment on Grabitz if the Examiner disagrees with Applicants, it does not appear that Grabitz remedies the failure of Nevalainen to disclose or suggest the claimed invention.

In view of the foregoing, Applicants respectfully maintain their position that the combination of references cited by the Examiner cannot be said to teach or suggest the claimed invention and, therefore, Applicants request that the rejection of claims 18, 19, 21, 22, 25-28 and 31-35, 39 and 40 based on those references be withdrawn. Similarly, given the failure of the three primary references to teach or suggest the claimed invention, claims 20 and 24 cannot be considered obvious over these references, even in view of Overton and Bedford, neither of which discloses, teaches or suggests a phytase-containing feed pellet having phytase activity of 14,000 FTU/g, as the Examiner acknowledges. Finally, the same can be said for the combination of references on which the Examiner based the rejection of claims 23, 39 and 40.



Conclusion

The application is considered in good and proper form for allowance. If there are any questions or comments regarding this Response or application, the Examiner is encouraged to contact the undersigned attorney as indicated below.

Respectfully submitted,

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